

REMARKS

Applicant hereby traverses the outstanding rejections and requests reconsideration and withdrawal in view of the remarks contained herein. Claims 1-9 and 21-36 have been withdrawn from consideration and canceled. Claims 37-45 have been added. Claims 10-20 and 37-45 are currently under consideration in this application.

Objection to the Disclosure

The serial numbers of the applications referenced in the specification have been substituted for the attorney docket numbers, as requested by the Examiner. In view of the amendments, Applicant respectfully requests that the Examiner withdraw the objection to the disclosure.

Rejection under 35 U.S.C. § 102 (Kordis)

Claims 10-11 and 13-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,476,495 to Kordis et al., (hereinafter Kordis).

It is well settled that to anticipate a claim, the reference must teach every element of the claim, see M.P.E.P. § 2131. Furthermore, in order for a prior art reference to be anticipatory under 35 U.S.C. § 102 with respect to a claim, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim,” see M.P.E.P. § 2131, citing *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). Applicant respectfully asserts that the rejection does not satisfy these requirements.

Claim 10 requires a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one conductor, and an outer layer having at least one conductor, wherein the inner layer and outer layer are within the unitary wall. At least these limitations are not shown in Kordis. The Examiner refers to mapping probe 18 shown in Figures 31-33 of Kordis as anticipating claim 10. Applicant respectfully disagrees with the Examiner’s interpretation of Kordis.

Kordis clearly shows in Figure 31 the structure of catheter body 96 of mapping probe 18, referenced with respect to Figure 1, which is described in detail at column 13, lines 31-55.

Catheter body 96 includes a center tube 106 made from a plastic material such as Pebax tubing. Id at lines 32-33. Two layers of copper signal wire 110 and 112 are wrapped around center tube 106 and each signal wire carries an outer insulating sheath. Id at lines 36-39. The layers 110 and 112 are separated by an insulation layer 114 of Teflon plastic or the like. Id at lines 39-44. Additionally, catheter body 96 includes a metalized plastic layer 116 that surrounds the second layer of signal wires 112. Id at lines 51-53.

The insulating layers of Kordis are formed using different materials and the layers of wires are clearly shown in Figure 31 as being formed in the gaps between materials 106, 114 and 116. As Kordis does not show a unitary lead body assembly wherein an inner layer having at least one conductor and an outer layer having at least one conductor are within the unitary wall, Applicant respectfully requests the rejection of claim 10 under §102(b) be withdrawn.

Claims 11, 13 and 14 each depend from claim 10 and thus inherit all of claim 10's limitations. Applicant, therefore, respectfully asserts that claims 11, 13 and 14 are allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Claim 15 requires a lead comprising a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one conductor, and an outer layer having at least one conductor, wherein the inner layer and outer layer are within the unitary wall. At least these limitations are not shown in Kordis. For the reasons set forth above, the catheter body shown in Figure 31 of Kordis does not show at least a unitary lead body assembly wherein an inner layer having at least one conductor and an outer layer having at least one conductor are within the unitary wall. As Kordis does not describe the invention of claim 10 in complete detail, Applicant respectfully requests the rejection of claim 15 under §102(b) be withdrawn.

Rejection under 35 U.S.C. § 102 (Diaz)

Claims 10-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,824,026 to Diaz, (hereinafter Diaz).

It is well settled that to anticipate a claim, the reference must teach every element of the claim, see M.P.E.P. § 2131. Furthermore, in order for a prior art reference to be anticipatory under 35 U.S.C. § 102 with respect to a claim, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim,” see M.P.E.P. § 2131, citing *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). Applicant respectfully asserts that the rejection does not satisfy these requirements.

Claim 10 requires a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one conductor, and an outer layer having at least one conductor, wherein the inner layer and outer layer are within the unitary wall. At least these limitations are not shown in Diaz. Diaz describes a catheter 10a which has embodiments shown in cross-section in Figures 3 and 5. The Catheter is comprised of a central flexible core 28. Column 4, lines 37-44. The core 28 has a layer of stranded fibers on its outer surface which are covered by insulating layer 17. Column 5, lines 6-24. Figure 5 shows a second and third layers of stranded fibers with an insulative layer 44 immediately covering the second layer of stranded fibers with the outer insulative layer 17 covering the third layer. Column 6, lines 14-34. Figures 3 and 5 show fibers 34 resting in the spaces between core 28 and insulating layers 44 and 17. The materials forming core 28 and insulating layers 44 and 17 are clearly distinct layers of materials as shown by the direction of the hatching on each layer. Nothing in Diaz suggests that the layers form a unitary wall as required in claim 10. Applicant, therefore, respectfully asserts that claim 10 is allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Claims 11-14 each depend from claim 10 and thus inherit all of claim 10's limitations. Applicant, therefore, respectfully asserts that claims 11-14 are allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Claim 15 requires a lead comprising a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one

conductor, and an outer layer having at least one conductor, wherein an inner layer having at least one conductor and an outer layer having at least one conductor are within the unitary wall. At least these limitations are not shown in Diaz. For the reasons set forth above, the catheter shown in Figures 3 and 5 of Diaz does not show at least a unitary lead body assembly wherein the inner layer and the outer layer are within the unitary wall. Applicant, therefore, respectfully requests the rejection of claim 15 under §102(b) be withdrawn.

Claims 16-20 each depend from claim 15 and thus inherit all of claim 15's limitations. Applicant, therefore, respectfully asserts that claims 16-20 are allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Rejection under 35 U.S.C. § 102 (Brownlee)

Claims 10-12, 14-17 and 19-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,772,693 to Brownlee, (hereinafter Brownlee).

It is well settled that to anticipate a claim, the reference must teach every element of the claim, see M.P.E.P. § 2131. Furthermore, in order for a prior art reference to be anticipatory under 35 U.S.C. § 102 with respect to a claim, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim,” see M.P.E.P. § 2131, citing *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). Applicant respectfully asserts that the rejection does not satisfy these requirements.

Claim 10 requires a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one conductor, and an outer layer having at least one conductor, wherein the inner layer and outer layer are within the unitary wall. At least these limitations are not shown in Brownlee. Brownlee describes a catheter body 70 shown in Figure 20 and described a column 12, lines 13-25. The catheter body is formed by four conductors 56, each conductor 56 separated by a layer of insulation 54. The preferred method of constructing catheter body 70 is to vertically extrude insulation directly onto each of the individual coils and then sliding the smaller coils into the longer coils prior to heat setting the catheter. Column 12, lines 19-25. Brownlee does not show a lumen nor does Brownlee show an inner layer having at least one conductor and outer layer having at least one conductor within a unitary wall. While the heat setting shrinks the

extrusion material into close contact with the conductors and holds the catheter body of Brownlee in its desired shape, nothing in Brownlee suggests the heat setting forms a unitary wall as required by claim 10. Heat setting of the type discussed by Brownlee is described in the background of the present application in paragraph 009. As Brownlee does not disclose at least the elements set forth above, Applicant respectfully asserts that claim 10 is allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Claims 11-12 and 14 each depend from claim 10 and thus inherit all of claim 10's limitations. Applicant, therefore, respectfully asserts that claims 11-12 and 14 are allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Claim 15 requires a lead comprising a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one conductor, and an outer layer having at least one conductor, wherein the inner layer and outer layer are within the unitary wall. At least these limitations are not shown in Brownlee. For the reasons set forth above, the catheter shown in Figure 20 of Brownlee does not show at least a unitary lead body assembly wherein an inner layer having at least one conductor and an outer layer having at least one conductor are within the unitary wall. Applicant, therefore, respectfully requests the rejection of claim 15 under §102(b) be withdrawn.

Claims 17 and 19-20 each depend from claim 15 and thus inherit all of claim 15's limitations. Applicant, therefore, respectfully asserts that claims 17 and 19-20 are allowable, for at least the reasons set forth, over the 35 U.S.C. §102(b) rejection.

Rejection under 35 U.S.C. § 103

Claims 13 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brownlee.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art cited must teach or suggest all the claim limitations. See M.P.E.P.

§ 2143. Without conceding the first or second criteria, Applicant asserts that the rejection does not satisfy the third criteria.

Claims 13 and 18 each require, through their dependencies from claims 10 and 15, respectfully, a unitary lead body assembly comprising a unitary wall having an inner portion that forms a lumen, an inner layer having at least one conductor, and an outer layer having at least one conductor, wherein the inner layer and outer layer are within the unitary wall. For the reasons set forth with respect to claims 10 and 15, respectfully, Brownlee does not describe these limitations. Applicant, therefore, respectfully asserts that claims 13 and 18 are allowable, for at least the reasons set forth, over the 35 U.S.C. §103 rejection.

New Claims

Claims 37-45 have been added and are supported by at least Figures 1, 2, and 7 of the present application. No new matter has been added.

Claims 37-42 require a structure formed by an electrically insulating material having a lumen formed therein, a first conductor operable to conduct an electrical signal and completely disposed in the structure formed by the electrically insulating material, the first conductor at a first distance from the lumen, and a second conductor operable to conduct an electrical signal and completely disposed in the structure formed by the electrically insulating material, the second conductor at a second distance, different than the first distance, from the lumen. Applicant respectfully asserts that the limitations set forth in claims 37-42 are not shown in the prior art cited by the Examiner.

Claims 43-45 require a source for generating an electrical stimulus, and a lead having at least one electrode for receiving the stimulus from the source, the lead being formed by a structure formed by an extrusion material having a lumen passing therethrough, at least a first conductor completely surrounded by the structure at a first distance from the lumen, and at least a second conductor completely surrounded by the structure at a second distance from the lumen, the at least a first conductor and at least a second conductor electrically connected between the source and a corresponding one of the at least one electrodes. Applicant respectfully asserts that the limitations set forth in claims 43-45 are not shown in the prior art cited by the Examiner.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 06-2380, under Order No. 03-009 from which the undersigned is authorized to draw.

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Respectfully submitted,

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